

**REMARKS**

Claims 41–50 are pending in this application. By this Amendment, claims 21–40 are canceled and claims 41–50 are added. Support for the new claims may be found, for example, in original claims 1–10. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

**I. Restriction and Election of Species Requirement**

In the March 23, 2007 Response to Restriction and Election of Species Requirement, Applicant elected Group I, which was defined by the Office Action as encompassing claims "drawn to a depolymerizing process of polylactic acid, wherein the polylactic acid is depolymerized in the presence of a hydrolase and producing a re-polymerizable oligomer" (see February 23, 2007 Office Action, page 2), and elected as a species the following:

1. the polylactic acid is depolymerized in the presence of a hydrolase in an organic solvent;
2. the polylactic acid is poly(DL-lactic acid);
3. the hydrolase is lipase;

with traverse.

Applicant respectfully submits that each of claims 41–50 recites a step of "depolymerizing polylactic acid in the presence of a hydrolase...thereby producing a re-polymerizable oligomer" and, thus, should be included in Group I. At least claims 41, 43, and 45–50 read on the elected species. At this time, no claims appear to be generic to all species.

Again, Applicant traverses the restriction and election of species requirement as being improper under PCT Rule 13.1, for the reasons previously made of record. As discussed above, each of claims 41–50 recites a step of "depolymerizing polylactic acid in the presence of a hydrolase...thereby producing a re-polymerizable oligomer." As will be discussed below, the applied references fail to teach or suggest such a step. Therefore, each claim

shares a common special technical feature, thus meeting the Unity of Invention standard set forth in PCT Rule 13.1. As such, any restriction or election of species requirement is improper and all claims and species must be examined.

## **II. Interview**

The courtesies extended to Applicant's representative by Examiner Lilling in the telephone interview held September 18, 2007, are appreciated. Arguments were presented that new claims 21–40 presented in the Amendment filed August 1, 2007, read on the elected invention. However, agreement was not reached.

## **III. Rejection under 35 U.S.C. §112, First Paragraph**

The Office Action rejects claims 1, 5, and 9, which correspond to new claims 41, 45, and 49, under the enablement requirement of 35 U.S.C. §112, first paragraph. Specifically, the Office Action asserts that the claims are not enabled because the cited references (1) D.F. Williams, "Enzymic hydrolysis of polylactic acid" ("Williams"), (2) J. Mauduit et al., "Hydrolytic degradation of films prepared from blends of high and low molecular weight poly(DL-lactic acid)s" ("Mauduit"), and (3) Sakai et al., "Isolation of a Thermophilic Poly-L-Lactide Degrading Bacterium from Compost and Its Enzymatic Characterization" ("Sakai") allegedly teach the same steps for degrading or depolymerizing polylactic acid polymers.

To make an enablement rejection, the Office Action has the initial burden to establish a reasonable basis to question the enablement provided by the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The fact that experimentation may be complex

does not necessarily make it undue if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983). In addition, "all that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art." *See* MPEP § 2164.08. However, not everything necessary to practice the invention needs to be disclosed, and "[i]n fact, what is well-known is best omitted." *Id.*

The basis for the enablement rejection purported by the Office Action appears to be that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. However, the Office Action fails to provide any indication of what essential enabling steps or components are missing from the disclosure and why one skilled in the art could not supply the information without undue experimentation. *See* MPEP § 2164.06(a).

Accordingly, Applicant respectfully submits that the Office Action has failed to meet its initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention. Thus, the rejection is improper, and should be withdrawn.

#### **IV. The Claims Distinguish Over the Applied References**

The Office Action asserts that Williams, Sakai, and Mauduit teach the same degradation or depolymerizing steps of the instant process. Applicant respectfully disagrees.

##### **A. Claim 41**

Claim 41, which corresponds to canceled claim 1, recites, "A depolymerizing process of polylactic acid, wherein the polylactic acid is depolymerized in the presence of a hydrolase in an organic solvent, thereby producing a re-polymerizable oligomer." Despite their asserted disclosures, Williams, Sakai, and Mauduit fail to disclose such a process.

Williams, Sakai, and Mauduit fail to disclose a method step of "depolymerizing polylactic acid in the presence of a hydrolase in an organic solvent, thereby producing a re-

polymerizable oligomer" (emphasis added) as required by claim 41. Although the May 28, 2007 Interview Summary alleges that Williams produces oligomers by the enzymatic hydrolysis of polylactic acid with esterases, this assertion is incorrect. Williams, at best, reports equivocal results with esterase degradation. Furthermore, Williams states, "No lactic acid was detected in the solution after exposure of polylactic acid to esterase but there was a slight weight loss and fall in pH. It is possible [but not conclusive] that there was a slight attack on the polymer without producing any products of sufficiently low molecular weight to be detected." D.F. Williams, *Enzymic hydrolysis of polylactic acid*, 10 MEP Ltd. 5, 7 (1981). Thus, Williams fails to teach polylactic acid enzymatic degradation with an esterase, fails to teach the use of an organic solvent, and fails to teach the formation of re-polymerizable oligomers.

Furthermore, although Mauduit discusses acid-catalyzed degradation of poly(DL-lactic acid), Mauduit does not disclose the use of a hydrolase or the formation of re-polymerizable oligomers.

Sakai discloses isolating thermophilic poly-L-lactide-degrading bacteria and reports on the enzymatic activity of PLLA depolymerase, but does not disclose the use of organic solvents, or the production of re-polymerizable oligomers.

For at least the reasons discussed above, claim 41 distinguishes over Williams, Mauduit, and Sakai.

**B. Claim 42**

Claim 42, which corresponds to canceled claim 2, recites, " A depolymerizing process of polylactic acid, wherein the polylactic acid is depolymerized in the presence of a hydrolase in a supercritical fluid, thereby producing a re-polymerizable oligomer." (emphasis added). Despite their asserted disclosures, Williams, Sakai, and Mauduit fail to disclose such a process.

Williams, Sakai, and Mauduit fail to disclose the use of a supercritical fluid. As discussed above, Williams, Sakai, and Mauduit also fail to disclose the production of repolymerizable oligomers. For at least these reasons, claim 42 distinguishes over Williams, Sakai, and Mauduit.

**V. Rejections Under 35 U.S.C. §103**

The Office Action rejects claims 1, 2, 5, and 9, which correspond to new claims 41, 42, 45, and 49, under 35 U.S.C. §103(a) as obvious over JP 2003-079388. ("JP '388"). Applicant respectfully traverses the rejection.

JP '388 is not available as prior art against the instant claims. The present application is the national phase of International Application No. PCT/JP03/09676, filed July 30, 2003. JP '388 was published on March 18, 2003. Because JP '388 is not a U.S. Patent or U.S. Patent Application Publication, and is not an international application designating the U.S. and published under Article 21(2) in the English language, JP '388 does not qualify as prior art with respect to this application under 35 U.S.C. §102(e). Additionally, because JP '388 was published on March 18, 2003, which is less than one year prior to the July 30, 2003 effective filing date for the present application, JP '388 does not qualify as prior art with respect to this application under 35 U.S.C. §102(b). Finally, because JP '388 is by the same inventor as the present application, JP '388 does not qualify as prior art with respect to this application under 35 U.S.C. §102(a).

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**VI. Allowable Subject Matter**

The Office Action indicates that claim 3 contains allowable subject matter and would be allowable if rewritten in independent form and if Applicant disqualifies JP '388 as prior art

against the pending claims by perfection the claim to the benefit of the August 5, 2002 filing date of foreign priority document JP 2002-227644 by submitting an accurate English-language translation of JP 2002-227644. Applicant appreciates this indication of allowable subject matter and submits that all pending claims are allowable for the reasons discussed above.

**VII. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



James A. Oliff  
Registration No. 27,075

Jeffrey R. Bousquet  
Registration No. 57,771

JAO:JRB

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**OLIFF & BERRIDGE, PLC**  
**P.O. Box 19928**  
**Alexandria, Virginia 22320**  
**Telephone: (703) 836-6400**

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